UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

FANCINE THOMPSON, on behalf of herself and all others similarly situated,	)	
Plaintiff,	)	
v.	)	Case No. 4:13CV00030 AGF
ALLERGAN USA, INC., ALLERGAN INC., and ALLERGAN SALES, LLC,	)	
Defendants.	)	

MEMORANDUM AND ORDER

This putative class action is before the Court on Defendants' motion (Doc. No. 15) to dismiss Plaintiff's first amended complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted, and alternatively, on federal preemption grounds. The Court heard oral argument on the motion on December 3, 2013, and thereafter received supplemental briefing by the parties. For the reasons set forth below, the Court concludes that Plaintiff has failed to state a claim under Missouri law. The Court concludes, alternatively, that Plaintiff's claims, which are all state law claims, are preempted by federal law.

BACKGROUND

Restasis is a prescription ophthalmic medication manufactured and sold by Defendants for the treatment of chronic dry eye. The medication is supplied in preservative-free vials that also serve as dispensers. Each vial of Restasis contains approximately 14 drops (400 microliters) of medicine, while the recommended dosage for

Restasis is one drop (28 microliters) twice a day. Restasis is packaged with an insert that states: "the emulsion from one individual single-use vial is to be used immediately after opening for administration to one or both eyes, and the remaining contents should be discarded after administration."

Plaintiff Francine Thompson brings this class action individually and on behalf of a class of Missouri consumers who purchased Restasis. Plaintiff's complaint is based on Defendants' alleged practice of "overfilling" Restasis dispensers so that consumers are forced to purchase more Restasis than they can use. Plaintiff alleges that Defendants set the price of the Restasis vials based upon the amount of medication in each vial and that if Defendants included smaller quantities of medication in the vials, the prescriptions would be less expensive and consumers would not have to spend so much on the medication. According to Plaintiff, Defendants increase profits by filling vials of Restasis with more medication than they knew consumers could use. These alleged profits, Plaintiff contends, constitute an economic harm to Plaintiff because there is no valid reason for Defendants to excessively overfill Restasis vials.

Count I of Plaintiff's first amended complaint alleges violation of the Missouri Merchandising Practices Act ("MMPA"), which provides that "[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce . . . is declared to be an unlawful practice." Mo. Rev. Stat. § 407.020. Count II claims that Defendants were unjustly enriched by their practice of overfilling Restasis

dispensers, and Count III, for money had and received, asserts that Defendants have received money from "deceptive and unfair practices." For relief, Plaintiff seeks actual damages to herself and class members, punitive damages, and declaratory and injunctive relief enjoining Defendants from continuing their practice of overfilling Restasis dispensers.

In support of their motion to dismiss the complaint, Defendants submit a Memorandum from the Federal Drug Administration ("FDA"), dated December 11, 2002 (Doc. No. 16-1), available at the FDA's public website. The Memorandum was related to the New Drug Application ("NDA") for Restasis. It addresses the FDA's concern that due to the overfill in each vial, patients may save the vial after a single dose, and use the remaining drug in the interest of saving money. The Medical Officer commented that the "additional volume" in each vial of Restasis "assists the patient in administering the correct amount of drug product" and "is also required for product stability"; and that the risk of using a vial beyond a single dose was "adequately communicated to practitioners, patients and caregivers within the Restasis package insert." (Doc. No. 16-1 at 4.)

Plaintiff also submits FDA Guidelines from January 2001, also publically available online, in which the FDA states that a "decrease in the fill volume" of a drug product "involves a change to the specifications and must be submitted in a prior approval supplement" for FDA approval. (Doc. No. 39-1 at 12.)

ARGUMENTS OF THE PARTIES

Failure to State a Claim

Defendants first argue that Plaintiff's claims, which are based on the assertion that there is no valid reason for the overfill, do not satisfy the plausibility standard of *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), in light of the FDA's opinion that the overfill assists patients in administering the correct dosage and is required for product stability. Defendants next argue that Plaintiff has not met the heightened pleading requirement of Federal Rule of Civil Procedure 9(b) for claims involving fraud. Defendants also argue that Plaintiff's complaint fails to allege an ascertainable loss, as required for a claim under the MMPA. Finally, Defendants argue that Plaintiff's equitable claims for unjust enrichment and money had and received fail because they are based on the same nonactionable conduct, Defendants were not unjustly enriched by Plaintiff's purchase of Restasis, and Plaintiff has an adequate remedy at law.

In response, Plaintiff argues that the FDA Memorandum, and Defendants' interpretation of it, are beyond the pleadings and therefore have no bearing on whether the complaint satisfies federal pleading requirements. Further, Plaintiff argues that Rule 9(b)'s heightened pleading requirements do not apply because the complaint does not allege fraud. Plaintiff contends that she states a cause of action under the MMPA because she sufficiently pled that Defendants' conduct was unfair, that the conduct caused an ascertainable loss, and that there was a causal connection between the conduct and the alleged loss. Plaintiff further argues that Defendants' profits and benefits were to Plaintiff's detriment and Defendants were thereby unjustly enriched. Finally, Plaintiff

argues that she states a claim for money had and received based on Defendants' deceptive and unfair practices, which money in equity and good conscience ought to be returned to consumers.

Federal Preemption

Defendants further argue that Plaintiff's claims are preempted by federal law because Defendants are unable to reduce the amount of medicine in each Restasis vial without prior FDA approval. Plaintiff argues that Defendants have not met their burden of establishing the affirmative defense of federal preemption. This issue has been the subject of supplemental memoranda by the parties in light of the United States Supreme Court's recent decision in *Mutual Pharmaceutical Co. v. Barlett*, 133 S. Ct. 2466 (2013). Plaintiff argues that whether or not the FDA would have approved a reduction in drops per vial is a factual issue that Defendants have not established. Furthermore, according to Plaintiff, it is unclear whether any reduction would be a "major change" requiring prior FDA approval.

DISCUSSION

Failure to State a Claim

To survive a motion to dismiss, a complaint must contain sufficient factual matter, which, if accepted as true, states "'a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). Although a complaint need not contain "detailed factual allegations," it must contain facts with enough specificity "to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. "Threadbare recitals of the elements of a cause of action, supported by mere

conclusory statements," will not pass muster. *Iqbal*, 556 U.S. at 678. In sum, this standard "calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of [the claim]." *Twombly*, 550 U.S. at 556.

The reviewing court must accept the plaintiff's factual allegations as true and construe them in the plaintiff's favor, but is not required to accept the legal conclusions the plaintiff draws from the facts alleged. *Iqbal*, 556 U.S. at 678; *see also Retro Television Network, Inc. v. Luken Comm'cns, LLC*, 696 F.3d 766, 768-69 (8th Cir. 2012). The Court must '"draw on its judicial experience and common sense,'" and consider the plausibility of the plaintiff's claim as a whole, not the plausibility of each individual allegation. *See Zoltek Corp. v. Structural Polymer Grp.*, 592 F.3d 893, 896 n.4 (8th Cir. 2010) (citation omitted)).

When ruling on a motion to dismiss under Rule 12(b)(6), the Court generally may not consider materials outside the pleadings. *Noble Sys. Corp. v. Alorica Cent., LLC*, 543 F.3d 978, 982 (8th Cir. 2008). It may, however, consider public records or materials that are necessarily embraced by the pleadings. *Id*; *Stahl v. U.S. Dep't of Agric.*, 327 F.3d 697, 700 (8th Cir. 2003). The Court concludes that it may consider the publically-available FDA Memoranda submitted by the parties.

The FDA Memorandum by Defendants, however, does not necessarily render implausible the basis for Plaintiff's claim. The memorandum speaks only to why *some* additional volume is necessary beyond the volume needed for two drops. It remains plausible that some volume beyond the volume needed for two drops, but less than 14 drops, may assist patients in administering the correct amount of the drug and maintain

product stability. The FDA memorandum, therefore, in and of itself, does not render Plaintiff's claim implausible.

To state a claim under the MMPA, Plaintiff must show that (1) she purchased the merchandise in question; (2) she purchased the merchandise for personal, family, or household use; (3) she suffered an ascertainable loss; and (4) the ascertainable loss was the result of an unfair practice. Mo. Rev. Stat. § 407.025(1); *Polk v. KV Pharm. Co.*, No. 4:09cv00588 SNLJ, 2011WL 6257466, at *4 (E.D. Mo. Dec. 15, 2011). It is undisputed that Plaintiff purchased Restasis for personal, family, or household use. The Court must therefore determine whether or not Plaintiff suffered an ascertainable loss.

An ascertainable loss of money or property is an essential element of a cause of action brought under the MMPA. *Grawitch v. Charter Commc'ns, Inc.*, No. 4:12CV01990 AGF, 2013 WL 253534, at *3 (E.D. Mo. Jan. 23, 2013). Missouri courts apply the "benefit of the bargain" rule when determining if a plaintiff has suffered an ascertainable loss under the MMPA. *Polk*, 2011 WL 6257466, at *5 (citing ***Sunset Pools of St. Louis, Inc. v. Schaefer,*** 869 S.W.2d 883, 886 (Mo. Ct. App. 1994)). The "benefit of the bargain" rule awards a prevailing party the difference between the value of the product as represented and the actual value of the product as received. *Id.*

The Court concludes that Plaintiff received the "benefit of the bargain" and has thus failed to claim an "ascertainable loss" under the MMPA. Plaintiff concedes that, according to the label, the dosage for Restasis is two drops, and that patients are instructed to discard the vial immediately after use. Plaintiff has thus not alleged that the Restasis was anything other than what it has always purported to be — a single-use vial.

Accordingly, Plaintiff has failed to allege that she did not receive the benefit of the medication for which she bargained. In short, Plaintiff bargained for a single dosage of Restasis, she received what was always purported to be a single dosage, and the medication performed as a single dosage.

Plaintiff cites *Plubell v. Merck & Co.*, 289 S.W.3d 707 (Mo. Ct. App. 2009), in arguing that the benefit-of-the-bargain rule only applies in misrepresentation cases. While *Plubell* was a misrepresentation case, *Polk* specifically discussed *Plubell* in applying the rule to a non-misrepresentation case under the MMPA. *Polk*, 2011 WL 6257466, at *5. The Court finds nothing in *Plubell* that limits the benefit-of-the-bargain test to a subset of MMPA claims that involve misrepresentation. Indeed, the fact that Plaintiff does not claim that Defendants made any type of misrepresentation supports the Court's conclusion that Plaintiff suffered no ascertainable loss.

Even if the benefit-of-the-bargain rule were inapplicable, Plaintiff has failed plausibly to claim an ascertainable loss under the MMPA. Plaintiff's claimed loss is based on the allegation "upon information and belief" that Defendants "set the price of the Restasis vials based upon the amount of medication in each vial." And "[i]f . . . Defendants included smaller quantities of medication in the Restasis vials, the prescriptions would be less expensive and consumers would not have to spend so much on the medication." But Plaintiff fails to set forth a plausible case to support this theory. Even assuming that less medication would produce a less expensive product for the consumer, the courts are not regulators of the fair market price of products.

Plaintiff's reliance on *Goldsmith v. Allergan, Inc.*, CV 09-7088 PSG EX, 2011 WL 2909313 (C.D. Cal. May 25, 2011), is not only unavailing, but also illustrates the flaw in Plaintiff's theory of recovery. In that case the court held that the plaintiff stated a claim against a drug manufacturer under a similar state statute where the defendant marketed single-use Botox vials as a "multi-use" product. Here, there is no allegation that Defendants in any way misrepresented what it was selling.

In sum, the allegation that including smaller quantities of medication in the Restasis vials would make it less expensive to consumers is without sufficient logical or factual foundation. Plaintiff has therefore failed to meet the ascertainable loss requirement for stating a claim under the MMPA. Similarly, her claims for unjust enrichment and money had and received also fail. *See Miller v. Horn*, 254 S.W.3d 920, 924 (Mo. Ct. App. 2008) (stating that an element of unjust enrichment is "that the enrichment was at the expense of the plaintiff"); *Springfield Land & Dev. Co. v. Bass*, 48 S.W.3d 620, 631 (Mo. Ct. App. 2001) (stating that an action for money had and received seeks to reach monies which ought to be paid to plaintiff).

Federal Preemption

The Supremacy Clause establishes that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. "Where state and federal law directly conflict, state law must give way. . . . [S]tate and federal law conflict where it is impossible for a private party to comply with both state and federal requirements." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577 (2011) (citations omitted); *accord Freightliner Corp. v.*

Myrick, 514 U.S. 280, 287 (1995) (cited with approval in *PLIVA*, 131 S. Ct. at 2577). "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *PLIVA*, 131 S. Ct. at 2579. "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id*. at 2581.

In *PLIVA*, the plaintiff contended that a generic drug manufacturer had breached a state tort-law duty to provide an adequate warning label. Federal law demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels. The Supreme Court held that because federal drug regulations, as interpreted by the FDA, prevented the manufacturer from independently changing its generic drugs' safety labels, it was impossible for the manufacturer to comply with both its state-law duty to change the label and its federal law duty to keep the label the same. *Id*. at 2577. Thus, the Court held, the plaintiff's state law claim was preempted. *Id.* at 2578. This was so even assuming that the generic manufacturer had a federal duty to ask the FDA for help in strengthening the corresponding brand-name label. *Id*.

Bartlett extended the holding of *PLIVA* to cover not just failure-to-warn claims, but also those claims that would require a redesign of a drug. *Bartlett*, 133 S. Ct. at 2476-77. The Supreme Court noted in *Bartlett* that "[o]nce a drug — whether generic or brand-name — is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or

in the specifications provided in the approved application.'" *Id.* at 2471 (citing 21 C.F.R. § 314.70(b)(2)(i)).

Thus, if Defendants were unable, under federal law, to independently lower the volume in each vial of Restasis to be in compliance with the state duties alleged by Plaintiff, Plaintiff's state claims would be prempted. FDA regulations provide that once a drug, whether generic or brand-name, is approved, the manufacturer is prohibited from making any major changes to the "qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application." 21 C.F.R. § 314.70(b)(2)(i)).

The Court concludes that reducing the amount of medicine in each Restasis vial is a major change requiring prior FDA approval. As noted above, FDA Guidelines from 2001 state that a "decrease in the fill volume" of a drug product "involves a change to the specifications and must be submitted in a prior approval supplement" for FDA approval. Even if FDA guidelines do not establish legally enforceable responsibilities, the Court agrees that a decrease in the fill volume of a drug product such as Restasis involves a change to the specifications under the plain meaning of the statute.

The Court does not find persuasive Plaintiff's argument that even if Defendants required FDA approval to change the volume in each vial, Plaintiff's claims are not preempted unless Defendants show by clear and convincing evidence that the FDA would have rejected such a change. This Court must follow the Supreme Court in rejecting the notion that "[m]anufacturers cannot bear their burden of proving impossibility because they did not even try to start the process that might ultimately have allowed them to

[comply with state law]." *PLIVA*, 131 S. Ct. at 2579. Applying this standard "would render conflict pre-emption largely meaningless because . . . [w]e can often imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it." *Id.* at 2579.

In sum, the Court finds that 21 C.F.R. § 314.70(b)(2)(i) made it impossible for Defendants independently to comply with the state law duty alleged in Plaintiff's complaint. Plaintiff's claims are therefore preempted under the Supremacy Clause.

CONCLUSION

Accordingly,

IT IS HEREBY ORDERED that Defendants' motion to dismiss Plaintiff's first amended complaint is **GRANTED**. (Doc. No. 15.)

A separate Judgment shall accompany this Memorandum and Order.

Audrey G. Fleissig

AUDREY G. FLEISSIG
UNITED STATES DISTRICT JUDGE

Dated this 28th day of January, 2014.